NADA Number: 140-338	
Trade Name	Naxcel® Sterile Powder
Sponsor	Pharmacia & Upjohn Co.
Ingredients	Ceftiofur Sodium
Species	Horse, not for meat production Cattle, beef Cattle, dairy Goat, no use class stated or implied Dog, no use class stated or implied Turkey, poults, day old Chicken, 1 day-old broiler chicks Sheep, no use class stated or implied Swine, no use class stated or implied
Routes of Administration	Intramuscular (sheep) Subcutaneous (dogs) Intramuscular (swine) Intramuscular (horse) Subcutaneous (turkeys) Subcutaneous (chickens) Intramuscular (cattle) Subcutaneous (cattle) Intramuscular (goats)
Dose Form	Liquid (solution)
Drug Form	Powder
Dispensing Status	RX
Patent Number	4464367
Exclusivity	Granted for the use in beef and dairy cattle for treatment of acute interdigital necrobacillosis. Granted for use of Ceftiofur sodium powder for the treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus (haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella cholerasuis, and Streptococcus suis Type 2. For the control of colibacillosis infections in day-old chicks (early chick mortality) associated with Escherichia coli organisms. Granted for the subcutaneous route of administration in the treatment of bovine respiratory disease and for the treatment of acute bovine interdigital necrobacillosis. Granted for the use in day-old turkey poults for the control of early mortality caused by E. coli organisms susceptible to ceftiofur. Granted for the use of ceftiofur sodium in an additional species (equine). This supplement is indicated for the treatment of respiratory infections in horses associated with Streptococcus zooepidemicus.

	522.313c Ceftiofur sodium. Specifications: Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents. Conditions of use: Swine Amount: 3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days. Indications: For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis, and Streptococcus suis. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Treated pigs must not be slaughtered for 4 days following the last treatment. Do not use in animals previously found to be hypersensitive to the drug. Use of doses in excess of those indicated or route of administration other than that recommended may result in illegal residues in tissues. Cattle (beef and dairy) Amount: Amount. 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Indications: Treatment of bovine respiratory disease (shipping fever, pneumonia) associated with Mannheimia haemolytica, P. multocida, and Histophilus somni in beef and dairy cattle; and for treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Treated cattle must not be slaughtered for 4 days following the last treatment. Do not use in animals previously found to be hypersensitive to the drug. Use of doses in excess of those indicated may result in illegal residues in tissues. Sheep Amount. 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Indications: For treatment of sheep respiratory disease (pneumonia) associated with M. haemolytica and P. multocida. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in tissues.

Dosage Amount, Indications & Limitations	Goats Amount. 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Indications: For treatment of caprine respiratory disease (goat pneumonia) associated with M. haemolytica and P. multocida. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Chickens (day-old chicks) Amount: 0.08 to 0.20 mg as a single subcutaneous injection in the neck. Indications: For control of early mortality associated with Escherichia coli organisms susceptible to ceftiofur in day-old chicks. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. As a single dose only. Turkeys (day-old poults) Amount: 0.17 to 0.5 mg as a single subcutaneous injection in the neck. Indications: For control of early mortality associated with E. coli organisms susceptible to ceftiofur in day-old poults. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. As a single dose only. Horses Amount: 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site. Indications: For treatment of respiratory infections in horses associated with Streptococcus zooepidemicus. Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption. Do not use in animals previously found to be hypersensitive to the drug. Dogs Amount: 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared, for 5 to 14 days. Indications: Treatment of canine urinary tract infections associated with E. coli and Proteus mirabilis. Limitations: Federal law restricts this drug to use by or on the order of a

	licensed veterinarian. Do not use in animals found to be hypersensitive to the drug.
Tolerances	A tolerance for residues of ceftiofur in edible tissue of poultry and sheep is not required. Tolerances in swine for desfuroylceftiofur(marker residue) in edible swine tissues are 0.25 part per million (ppm) in kidney (target tissue), 3 ppm in liver, and 2 ppm in muscle. Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible cattle tissues at 0.4 ppm in kidney (target tissue), 2 ppm in the liver, 1 ppm in muscle, 0.1 ppm in milk.